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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/677,962	10/03/2000	Mark B. Lyles	068351.0110	4536
7590	02/27/2004		EXAMINER	
Baker Botts, L.L.P. One Shell Plaza 910 Louisiana Houston, TX 77002-4995			WOO, JULIAN W	
			ART UNIT	PAPER NUMBER
			3731	
			DATE MAILED: 02/27/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/677,962	LYLES ET AL.
	Examiner	Art Unit
	Julian W. Woo	3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 03 October 2000.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 7-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 7-22 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 7 and 10-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Yasukawa-et al. (5,629,186). Yasukawa et al. disclose, in col. 3, lines 34-53; col. 4, lines 5-13; col. 11, lines 34-41; col. 12, lines 1-2, and col. 12, lines 18-21, a drug delivery system with a composition manufactured from fused silica fibers with a plurality of voids (31) having a predetermined mean void size and one or more drugs or cells, where the composition has a density in the ranges as claimed.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Art Unit: 3731

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claims 7-9, 16-20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seare, Jr. (5,681,572) in view of Yasukawa et al. (5,629,186). Seare, Jr. discloses the invention substantially as claimed. Seare, Jr. discloses, in col. 14, line 20 to col. 15, lines 9 and col. 15, lines 54-65, a drug delivery system with a composition manufactured from ceramic fibers or particles, one or more drugs (including antibiotics), and one or more biodegradable polymers (polyvinyl alcohol, polyglycolic acid, or polylactic acid), where the composition can have various porosities or densities. However, Seare, Jr. does not disclose a composition manufactured from silica fibers and a density that is between 6 pounds per cubic foot and about 7 pounds per cubic foot. Seare, Jr. does not disclose spherical particles having a mean diameter of about 300 microns to about 500 microns. Seare, Jr. also does not disclose the drugs as claimed in claims 17-20. Yasukawa et al. teach the use of ceramic silica fibers in a drug delivery system. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Yasukawa et al., to apply silica in the system of Seare, Jr. Silica is a biocompatible material that can optimize porous structures for cell growth and drug delivery. The types of drugs, particle size, and the density of the composition are matters of design choice, so the drugs as claimed, spherical particles having a mean diameter of about 300 microns to about 500 microns, or a density that is

between 6 pounds per cubic foot and about 7 pounds per cubic foot can be chosen according to the desired therapeutic effects desired from the drug delivery system.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached at (703) 308-2496.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703) 308-0858. The official FAX number is (703) 872-9306.



Julian W. Woo
Primary Examiner

February 22, 2004